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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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|-----------------|-------------|----------------------|---------------------|

09/503,656 02/14/00 BAUMZWEIGER

W 50065

EXAMINER

QM12/0509

Nathan Boatner Attorney
PMB 692 7095 Hollywood Blvd
Los Angeles CA 90028

ASTORINO, M

ART UNIT

PAPER NUMBER

3736

DATE MAILED:

05/09/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/503,656

Applicant(s)

Baumzweiger

Examiner

Michael C Astorino

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 8-10 and 24-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 7 and 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, and 6-49, drawn to a method of diagnosing a disorder in the brain stem, classified in class 600, subclass 300.
 - II. Claims 4-5, and 50-77, drawn to a method of treatment of a disorder brain stem, classified in class 600, subclass 300.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions diagnosing and treatment has different modes of operation, different functions and different effects.

2. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: method of diagnosing a disorder in the CNS and brain stem of the body.

Species II: method of diagnosing a disorder in the brain stem and limbic system of the body.

Species III: method of diagnosing a disorder in the brain stem and one or more other parts of the body.

Species IV: method of treatment a disorder localized in the CNS and brain stem of the body.

Species ~~IV~~ method of treatment a disorder in the brain stem and at least one other part of the body.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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4. During a telephone conversation with Nathan Boatner on 4/27/01 a provisional election was made without traverse to prosecute the invention of method of diagnosis of the brain stem, claims 1-3, and 6-49. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-5, and 50-77, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Furthermore Species I was elected claims 1, 6-7, and 11-23, a method of diagnosis of a disorder of the CNS that localizes the disorder in the brain stem. Concurrently claims 2-3, 8-10, and 24-49 have been withdrawn.

Specification

5. Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Reference to a "Microfiche Appendix": See 37CFR 1.96(c) and MPEP § 608.05. The total number of microfiche and the total number frames should be specified.
- (e) Background of the Invention: The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

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- (f) **Brief Summary of the Invention:** A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) **Brief Description of the Several Views of the Drawing(s):** A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) **Detailed Description of the Invention:** A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) **Claim or Claims:** See 37 CFR 1.75 and MPEP § 608.01(m). **The claim or claims must commence on separate sheet.** (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.
- (j) **Abstract of the Disclosure:** A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims.
- (k) **Drawings:** See 37 CFR 1.81, 1.83-1.85, and MPEP § 608.02.
- (l) **Sequence Listing:** See 37 CFR 1.821-1.825.

Claim Objections

6. Claim 6 is objected to because of the following informalities: the use of a colon in line 21 is improper. Appropriate correction is required.
7. Claim 7 is objected to because of the following informalities: the use of a colon in line 11 is improper. Appropriate correction is required.
8. Claims 11-22 objected to because of the following informalities: punctuation is incorrect, please use a period at the end of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
10. Claims 7 and 11-23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. Claims 6 and 7 appear to be identical to each other and are duplicates. Please cancel claim 7.
12. Claim 11-23 recite the limitation "wherein one of the steps" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claims 1, 11-21, and 23 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by John ('619).

John discloses the use of a diagnosing device of a brain stem wherein clinical tests for heart rate, one or more cranial nerves, spinal cord damage, increased motor tone, peripheral nerve damage, abnormal reflexes, infection, immune system disorder, abnormal coagulation of blood, PO2 in venous blood, and making a neuro-psychiatric exam of a patient (columns 1-2).

15. Claims 1, and 22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Don ('112).

Don discloses the use of a diagnosing device of a brain stem wherein clinical tests for using an MRI test on the brain stem and limbic system of a patient (columns 1-2).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in further view of Don.

John discloses the use of a diagnosing device of a brain stem wherein clinical tests for heart rate, one or more cranial nerves, spinal cord damage, increased motor tone, peripheral nerve damage, abnormal reflexes, infection, immune system disorder, abnormal coagulation of blood, PO2 in venous blood, and making a neuro-psychiatric exam of a patient (columns 1-2), but John does not disclose the use of a MRI test for diagnosing a brain stem disorder. However Don, a reference in an analogous art, discloses the use of a MRI test for diagnosing a brain stem disorder (column 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the Brain scan function system of John, and the MRI Brainstem testing device of Don to maintain a ABR device wherein greater accuracy would be achieved.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C Astorino whose telephone number is 703-306-9067.

The examiner can normally be reached on Tuesday-Friday, 8:00AM to 5:00PM.



Michael Astorino
May 7, 2001



JOHN P. LACYK
PRIMARY EXAMINER